UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	))))	MDL NO. 1456 Civil Action No. 01-12257-PBS Subcategory Case No. 06-11337-PBS
THIS DOCUMENT RELATES TO: *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Schering Corporation, Schering-Plough Corporation and Warrick Pharmaceuticals Corporation*, Civil Action No. 09-CV-10547, and *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Schering Corporation, Schering-Plough Corporation and Warrick Pharmaceuticals Corporation*, Civil Action No. 00-CV-10698	))))))))))))))	Judge Patti J. Saris

THE CITY OF NEW YORK AND NEW YORK COUNTIES' RESPONSE AND OBJECTION TO THE MOTION TO APPROVE THE PROPOSED SETTLEMENT BETWEEN CALIFORNIA, FLORIDA AND RELATOR VEN-A-CARE OF THE FLORIDA KEYS ON BEHALF OF ITSELF AND THE UNITED STATES AND SCHERING-PLOUGH, SCHERING & WARRICK

The City of New York and New York Counties (hereinafter "the NY Counties") in MDL 1456, by and through their attorneys of record, file this response and objection to the motion to approve the proposed Settlement Agreement and Release filed on August 7, 2009 by Schering-Plough Corporation, Schering Corporation, Warrick Pharmaceuticals Corporation, Ven-A-Care of the Florida Keys, Inc. ("VAC"), and the State of California[1] [Dkt. No. 6359] (hereinafter the "Settlement").

[1] The Settlement is "intended to resolve … the claims encompassed by Ven-A-Care's Federal False Claims Act actions, and the California and Florida actions against

The Settlement and papers filed in connection therewith, as drafted, are flawed in numerous material respects.

1. Settlement Seeks An Improper Advisory Opinion

The advocates to the Settlement ask this Court for an "advisory opinion" on, *inter alia*, the propriety of Schering's price reporting practices for the Schering branded products ("Schering Covered Drugs"). None of the original VAC complaints asserted a claim against Schering concerning these products. There is not even a claim asserted in the VAC Amended Complaint, filed July 24, 2009 [Dkt. No. 6292], concerning the Schering Covered Drugs. Indeed, the VAC Amended Complaint specifically alleges that there is no cause of action in connection with the Schering Covered Drugs. Paragraph 76 reads as follows:

> "Ven-A-Care has investigated additional drugs marketed by the DEFENDANTS during the relevant time period. Those additional drugs are hereinafter referred to as "Schering Brand Drugs" and are listed in Exhibit F. Ven-A-Care has determined that the states' Medicaid programs did not incur substantial damages for the Schering Brand Drugs because the DEFENDANTS did not materially misstate the drug price report for those drugs. Ven-A-Care has determined that the states' Medicaid programs did not incur substantial damages for the Schering Brand Drugs because the DEFENDANTS caused AWPs to be reported that were within 25% of the Wholesaler's Acquisition Cost (subject to at most a 5% discount of WAC) and thus did not materially misstate the drug price report for those drugs."

This conclusory statement from paragraph 76 is the only (even arguably) substantive reference to Schering Covered Drugs in the entire VAC Amended Complaint. VAC's original mission, evident from the Amended Complaint as well as those that preceded it, was to seek

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Schering/Warrick." *See* Joint Memorandum in Support of Motion for Approval of the Settlement between California, Florida and Relator Ven-A-Care of the Florida Keys on behalf of itself and the United States and Schering-Plough, Schering and Warrick" [Dkt. No. 6360] ("Joint Mem.") at 1. Yet, the State of Florida is not a signator to the Joint Mem. Only California, VAC and the Schering defendants have signed.

redress concerning a few Albuterol NDCs (defined as the "Specified Products" and listed in VAC Amended Complaint Exhibit A). VAC simply has not presented a case or controversy on Schering Covered Drugs to this Court. Entry of the proposed findings would be improper under these circumstances. *See Overseas Military Sales Corp. v. Giralt-Armada*, 503 F. 3d 12, 16 (1st Cir. 2007); *Osediacz v. City of Cranston*, 414 F.3d 136, 139 (1st Cir. 2005). The Constitution's case or controversy requirement prevents federal courts from issuing advisory opinions and "limits[s] the business of federal courts to questions presented in an adversary context." *Giralt-Armada*, 503 F.3d at 17 (quoting *Flast v. Cohen*, 392 U.S. 83 (1968)).

2. The Proposed Findings Are Unsupported By Schering's Expert Or Record

The advocates of the Settlement also propose entry of the Findings of Fact ("Proposed Findings"). Insofar as these Proposed Findings concern the Schering Covered Drugs, they are unsupported by the conclusions of Schering's own expert. Sumanth Addanki, Ph.D., has found that of the 30 Schering Covered Drugs included in Exhibit F to the VAC Amended Complaint, 20 have annual spreads for certain years in excess of 30%. *See* Affidavit of Sumanth Addanki, sworn to February 20, 2008 [Dkt. No. 5299] ("Addanki Aff. I") at _Exh. 3; Affidavit of Sumanth Addanki, sworn to August 6, 2009 [Dkt. No. 6361] ("Addanki Aff. II") at Exh. 3. This Court has applied a 30% yardstick for both liability and discovery purposes in assorted contexts. *See, e.g., In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 93, 101 et seq. (D. Mass. 2007) Thus, even by Schering's own expert's account, it cannot be "found" that there is no liability or damage whatsoever associated with the Schering Covered Drugs.

The Proposed Findings are otherwise unsupported or premature. First, it cannot be stated on the instant record that the Schering Covered Drugs pass the WAC List Price Test. The proper

approach to that test is unresolved given the pendency of GlaxoSmithKline's Motion for Partial Summary Judgment in the NY Counties case.[2] Until it is determined which data properly should be considered in the WAC List Price Test, it cannot be fairly or accurately stated, let alone "found" by this Court, that any NDC passes or fails this test. (As of this filing, the parties to the GSK motion await scheduling of what is likely to be the final oral argument on the GSK motion.).

Second, it appears from the filings in connection with the Settlement that Ven-A-Care may have concluded there are no damages associated with the Schering Covered Drugs based on the spread between AMP and AWP or based on the McKesson Servall Prices available to VAC through Econolink.[3] The conclusion is curious given that, as noted above, Schering's own expert has identified 20 Schering Covered Drugs which had spreads in excess of 30% on an annual basis in certain years. In addition, and as set forth in plaintiffs' motion to intervene for the limited purpose of objecting to the objecting to the Ven-A-Care/Schering/Warrick Proposed Settlement [Dkt. No. 6289] ("NY Counties' Motion to Intervene") ("A" hereto and incorporated herein), on the instant record, the Court cannot find that Schering's AMPs are appropriate proxies for ASPs for purposes of an ASP/AWP spread test. ASP, as defined by 42 U.S.C. § 1395w-3a(c), is to be calculated as a net figure that accounts for all rebates. "[S]uch price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1396r-8)." *Id*. at § 1395w-3a(c)(3). The parties to the Settlement do not present any evidence that

[2] *See* briefing and supplemental briefing on GSK's Motion for Partial Summary Judgment [Dkt. Nos. 5706, 5707, 5708, 5892, 5893, 5894, 5940, 5960, 6155, and 6250].

Schering AMPs are calculated in such fashion. Therefore, on the instant record this Court cannot "find" that Schering/Warrick AMPs can serve as a proxy for an ASP in the context of an ASP/AWP spread test.[4]

The Servall Econolink Prices, as this Court may recall from briefing on defendants' motions to dismiss the NY Counties' Complaints, are prices offered to a GPO comprised of independent pharmacies. They are conservative estimates of true AWPs given the relative lack of bargaining power of independent pharmacies when it comes to negotiating discounts and given the fact that they do not include all rebates. Moreover, the Servall prices have not been presented to the Court in any sort of organized fashion in connection with or as a basis for the instant Settlement. The Servall prices therefore are hardly an adequate foundation on which to conclude that there is no liability whatsoever for the Schering Covered Drugs.

In addition to being improper and premature given the uncertainty of the WAC List Price Test and the lack of a proper record on AWP Spread Test, entry of the Proposed Findings would be highly prejudicial to the NY Counties given that their case against Schering/Warrick includes the same Covered Drugs and Conduct as are at issue in the Proposed Settlement and Order and given that the above tests are being actively litigated. *See* Comparison of Schering drugs at issue in the NY Counties case with Schering Covered Drugs included in Proposed Settlement (attached as Exhibit A to NY Counties' motion to intervene). The NY Counties are pressing for discovery from Schering and VAC regarding (a) the data reviewed, exchanged and relied upon in

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[3] Plaintiffs have served discovery on Schering and a subpoena on Ven-A-Care to determine whether this is, in fact, the sole basis for the VAC conclusions. Responses to that discovery are due before the September 25, 2009 hearing.

[4] The New York Counties again emphasize that they are not arguing or implying that Schering/Warrick miscalculated their AMPs. The question is only whether Schering/Warrick AMPs can serve as a proxy for ASP in the context of an ASP/AWP spread test.

connection with the Settlement, and (b) how Schering's AMPs are calculated. The NY Counties are also pressing Schering for all responsive discovery including sales and transactional data on the 20 drugs for which Dr. Addanki calculated annual spreads in excess of 30% for certain years.[5]

Third, the record does not support entry of any finding with regard to New York Medicaid's expectations and the 30% yardstick. There is not a stitch of evidence in the record at this point as to New York Medicaid's expectations and, as this Court noted during the July 24, 2009 hearing, the ultimate applicability of a 30% yardstick has not yet been decided in the New York Counties' case. *See* Transcript of July 24, 2009 Scheduling Conference at 24:19-23 (New York cases have "reserved their rights to push back, if I'm remembering correctly, for the extra 5 percent') It would highly prejudicial and entirely improper for a finding to be entered that New York Medicaid had a 30% expectation in the absence of any record support to that effect and when the issue remains unresolved in the New York Counties' case.

3. $55 Million Is Not Fair, Reasonable or Adequate

It is the NY Counties' understanding that the scheduled September 25, 2009 hearing will focus on whether the Department of Justice has veto power over this deal. *See*, *e.g*, Transcript of July 24, 2009 Scheduling Conference at 15-24. To that end, the NY Counties are not, at this time, submitting their expert analysis as to why a $55 million settlement of Schering/Warrick claims is not fair, reasonable or adequate. With the Court's permission, the NY Counties expressly reserve the right to submit that report when and if a briefing schedule and/or evidentiary hearing on the adequacy of the proposed amount is set. The NY Counties will

however summarize here their argument as to why $55 million, on its face, is not fair, reasonable or adequate for the contemplated release of all federal claims.

VAC believes there are no damages associated with the Schering Covered Drugs and has asserted no claims concerning the Schering Covered Drugs. *See* VAC Amended Complaint at ¶76 and Causes of Action; *see also* discussion at (1) *infra*. Thus, the $55 million is being paid to resolve claims for the NDCs associated with Subject Albuterol Products and the other Warrick drugs (belatedly) added to the VAC case. *See* VAC Amended Complaint at Exhibit E.

We know from VAC counsel's remarks during July 24, 2009 hearing that only $23 of the $55 million settlement is being allocated to the Federal Government. The amount is woefully inadequate from the NY Counties' perspective given their valuation of the damages incurred in connection with Warrick's pricing practices by the New York County Medicaid Program as a whole. A $23 million payment to the Federal Government would translate into approximately $2.3 million for release of New York's federal share of all Warrick claims.

New York Medicaid expenditures in the Warrick products at issue in the NY Counties' Case, during the relevant period of 1997 - 2005, were over $165 million. VAC alleges that spreads for these products range from 50% to 764%. *See* VAC Amended Complaint at Exhs. A and E. Even the most conservative formulas produce damages to the Federal Government in connection with its contributions to the New York Medicaid program that are far in excess of the $2.3 million the Settlement would provide.

As to Schering Covered Drugs, Schering's own expert concludes that 20 Schering Brand drugs had spreads on annual basis in certain years that were in excess of 30%. Addanki II at

[5] It is entirely unclear whether anyone advocating this Settlement has reviewed such pricing data. Certainly there is no record of such a review before this Court.

Exh. 3. Yet, VAC assigns zero value to claims for these drugs and states, in its Amended Complaint that under the Court's rulings there is no liability for these or any Schering Drugs. VAC Amended Complaint at ¶ 76. VAC specifically alleges that "the states' Medicaid programs did not incur substantial damages for the Schering brand drugs because DEFENDANTS did not materially misstate the drug price report for those drugs." *Id.* The Court's rulings and the record do not support this allegation or the entry of findings consistent with it, as set forth in (2) above. The NY County Medicaid programs spent $215 million in the over-30% Schering Covered Drugs between 1997-2005. Even a 1% overcharge translates into $2 million. It is not for the advocates of this Settlement to conclude this amount to be insubstantial or immaterial from the NY Counties' perspective.

4. **Schering Understates the Extent of its Access to Federal Witnesses**

In the Settlement submissions and elsewhere, Schering claims that it has not had sufficient access to federal government witnesses and that certain process and procedural issues are limiting its ability to develop its defense to claims on the Federal Share. *See, e.g.*, Affidavit of Beth Trent, sworn to August 7, 2009 at ¶19 [Dkt. No. 237]. Schering is understating the amount of access it has had. Submitted together herewith is the Declaration of Joanne M. Cicala, with exhibits, dated August 28, 2009 ("Cicala Dec.) which puts before the Court what the NY Counties believe to be a complete listing of all Federal witnesses who have been deposed in MDL 1456. This Declaration, together with its exhibits A- DD, confirms the prior representations of the NY Counties that 27 CMS witnesses have been deposed by defendants in MDL 1456. *See* Cicala Dec. at ¶6 and Exh. A thereto. In addition, there have been 4 OIG witnesses deposed. *Id.* Many of these depositions were attended by Schering Counsel. *Id.* at Exhibit A. Those that were not, could have been and are, in any event, usable for all purposes in

these proceedings pursuant to the operative MDL Protective Orders. *Id.* at ¶¶ 8, 9 and Exhibits C and D thereto. Schering cannot reasonably be heard to complain about access to federal government witnesses.

CONCLUSION

For all the foregoing reasons, the NY Counties respectfully request that the Court reject the Settlement as drafted.

Dated: August 28, 2009

Respectfully submitted,

City of New York and New York Counties in MDL 1456 except Nassau and Orange by

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CERTIFICATE OF SERVICE

I, Jocelyn R. Normand, hereby certify that I caused a true and correct copy of the foregoing to be served on counsel of record via electronic service pursuant to paragraph 11 of Case Management Order No. 2, by sending a copy to LexisNexis File and Serve for posting and notification to all parties.

Dated: August 28, 2009

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